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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/743,118

12/22/2003

Fred Wehling

208-015USI

7497

27791

7590

08/22/2006

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EXAMINER

SAMALA, JAGADISHWAR RAO

ART UNIT

PAPER NUMBER

1618

DATE MAILED: 08/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/743,118	WEHLING ET AL.	
	Examiner	Art Unit	
	Jagadishwar R. Samala	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-36 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-36 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. Claim 33 recites the limitation "treating human" in line 1. There is insufficient antecedent basis for this limitation in the claim. It is unclear what "treating human" means.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-26, 31 and 32 are rejected under 35 U.S.C. 102(b) as being anticipated by Murpani et al., (US 2003/0161875 here after '875) or Needleman et al.,(US 5,993,854 here after '854) The '875 patent discloses an fast dissolving tablets for oral administration comprising a therapeutically effective amount of drugs, which disintegrate quickly in mouth. The therapeutic effervescent composition may additionally contain conventional additives such as flavoring agents, sweeteners, lubricants colorants and glidants. The flavoring agents include both natural and artificial flavors such as vanilla, cinnamon, various fruit flavors, peppermint, menthol essential oils such as thymol, eucalyptol and methyl salicylate and the like (see page 2, Para 0035). The '875 patent discloses an composition comprising lubricants selected from

Art Unit: 1618

talc, magnesium stearate, calcium stearate, stearic acid, magnesium lauryl sulphate, hydrogenated vegetable oils and soluble lubricants like sodium benzoate, a mixture of sodium benzoate and sodium acetate, sodium chloride, leucine, sodium stearyl fumarate and PEG 4000 (see page 2, para 0031). The '875 patent discloses an composition comprising coloring agent selected from any colorant used in pharmaceuticals which is approved and certified by the FDA (see page 2, para 0034). The '875 patent further discloses an composition comprising an sweeteners of both natural and artificial ones. The sweeteners include, water-soluble sweetening agents such as mono saccharides, disaccharides and polysaccharides, partially hydrolyzed starch, or corn syrup solids and sugar alcohols, such as sorbitol, xylitol, mannitol and mixtures thereof (see page 2, para 0036). These disclosures render the claims anticipated.

The '854 patent discloses an tablet of aroma releasing composition comprising an effervescent agent, surface active agents, binders, buffers, oils and fats, high molecular weight compounds and thereof. The flavoring agents include animal perfumes such as musk oil, civet, castreum, plant perfumes such as sandalwood oil, rosemary oil, peppermint oil, eucalyptus oil, menthol, camphor and other excipients used for modified fragrance agents (see column 3, lines 33-60). The '854 patent discloses a composition comprising a lubricants include polyethylene glycol, PEG – 150 and sorbitol, but various lubricating agents may be used in the inventive composition (see column 4, lines 8-12). The '854 patent also discloses a method of evaluation of thickness, hardness, dissolution time by placing the tablet in water and studying the fragrance impact (see

Art Unit: 1618

column 4, lines 55-65 and column 5, lines 30-54)). These disclosures render the claims anticipated.

Claims 1,27-30 are rejected under 35 U.S.C. 102(b) as being anticipated by Rockliffe et al., (US 4,471,871 here after '871). The '871 patent discloses a method of packaging of tablets in a sealed pouch or packet adapted to be torn open when required for use (see abstract). The '871 patent further discloses a safe device of packaging kit for tablet, in such a manner that the tablets are contained with in an air tight sealed container which is impervious to the ingress of moisture (see column 6, lines 1-3).

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1-26 are rejected under 35 U.S.C. 103 (a) as being unpatentable over (Gioffre et al, US 4,627,972 here after '972) in view of (Schobel et al, US 4,687,662 here after '662). The claims are drawn to a therapeutic composition comprising a carrier and an effervescent agent. The carrier allows for a modified controlled release of the effervescent composition.

4. The '972 patent discloses an effervescent composition comprising menthol, eucalyptus oil and effervescent agent (see column 4, lines 22-56).

Art Unit: 1618

The '972 reference fails to teach specifically the formulation in the form of tablet which dissolves in water having temperature of 38⁰C.

Schobel et al, (US 4,687,662 here after '662) while disclosing a therapeutic effervescent composition, teaches that the composition can be either in the form of tablets or powders which upon addition to water dissolve to produce a clear solution.

The '662 reference further teaches that the dissolution of the tablet occurs when added to water at 22⁰C (see column 10, lines 63-64).

Regarding claims 35 and 36, it is the position of the examiner that the temperature of the water does not input patentability of the claims. The prior art provides a method, where an effervescent tablet when dissolved in water produces a solution which makes it uniquely desirable for use as a mouthwash (William P. Milkvy et al., US 3,772,431 see column 1 lines 24-26). Indeed the resulting effervescent mouthwash solution will have the dual role of producing an astringent mouthwash effect and desensitizing action, and which form will lend for long lasting plaque control, decay control, anti-microbial action, breath sweetening whitening and thereof.

It would have been obvious to one of ordinary skill in the art to further to modify the composition of Gioffre in the form of tablets with the reasonable expectations success, since Schobel teaches that the effervescence composition made either as tablet or powders will dissolve in water. Since Schobel teaches that the tablets dissolves in water at 22⁰C, one of ordinary silk in the art, that it will dissolve even at high temperature, such as claimed at 38⁰C.

Art Unit: 1618

Given the general teaching of dissolution of effervescent tablet to provide a clear solution, which makes it uniquely desirable for use as mouthwash as disclosed by William P. Mikvy, one of ordinary skill in the art would have been motivated to employ improved tablet composition comprising effervescent agent as disclosed by Schobel because the use of improved effervescent mouthwash tablets is common in the art of mouthwash solutions to provide a desired effervescent tablet with mouthwash applications as shown by William and Schoble.

Conclusion

No claims are allowed at this time.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jagadishwar R. Samala whose telephone number is (571)272-9927. The examiner can normally be reached on 8.30 A.M to 5.00 P.M.

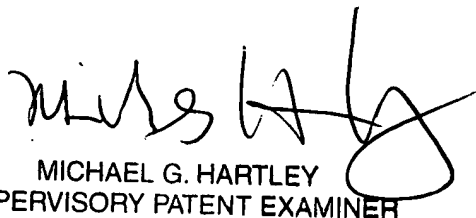
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571)272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1618

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Jagadishwar R Samala
Examiner
Art Unit 1618

sjr



MICHAEL G. HARTLEY
SUPERVISORY PATENT EXAMINER